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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,880	07/21/2003	Charles Jason Barnett	60063USDIV2	9955
22847	7590	09/28/2005	EXAMINER	
SYNGENTA BIOTECHNOLOGY, INC.			KIM, YOUNG J	
PATENT DEPARTMENT			ART UNIT	
3054 CORNWALLIS ROAD			PAPER NUMBER	
P.O. BOX 12257			1637	
RESEARCH TRIANGLE PARK, NC 27709-2257			DATE MAILED: 09/28/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,880

Applicant(s)

BARNETT ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-12 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8-11 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 8/6/2004.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

ML

DETAILED ACTION

Preliminary Remark

The preliminary amendment received on July 21, 2003, canceling claims 4-7, 13-16, and 20-46 is acknowledged.

Claims 1-3, 8-12, and 17-19 are pending and are under prosecution therefore.

Information Disclosure Statement

The IDS received on August 6, 2004 is acknowledged.

A signed copy of the PTO-1449 is attached hereto.

Drawings

No drawings have been filed in the instant application.

Claim Interpretation

With regard to claim 2, which recites the phrase, “[a] pair of oligonucleotide primers, wherein said pair consists of said primer of claim 1,” has been interpreted to mean that the pair of primer consists of two oligonucleotides consisting of SEQ ID N: 27.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim referring to two sets of claims to different features. See MPEP § 608.01(n), example B(3). Accordingly, the claim 12 *has not been further treated* on the merits.

Claim 11 appears to be a redundant claim 10. Claim 10 recites that the claim is drawn to a method for detecting *Cladosporium carpophilum*, wherein the method step recites, “isolating

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DNA from a plant tissue *infected with Cladosporium carpophilum*." Hence, claim 11 reciting that method of claim 10, wherein *Cladosporium carpophilum* is redundant, not further limiting the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 11 recite the limitation "said fungal pathogen." There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-11, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

MPEP 2164 states that under requirement criteria, the specification describe how to not

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only make, but use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The standard for determining whether the specification meets the enablement requirement was cast in in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

Nature of the Invention:

The nature of the invention relates to a method of detecting a specific species of a fungal pathogen (in the instant case, *Cladosporium carpophilum*) by isolating a DNA from a plant tissue and amplifying a region via use of primers, wherein the presence of the amplified product is indicative of the presence of *Cladosporium carpophilum*.

The enablement issue at hand is whether a primer (consisting of SEQ ID NO: 27) or a primer set (consisting of two oligonucleotide consisting of SEQ ID NO: 27), or a primer pair consisting of SEQ ID NO: 1 and SEQ ID NO: 27, which is non-specific for *Cladosporium carpophilum* can be employed in a method of detecting *Cladosporium carpophilum*.

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Breadth of the Claims:

The breadth of the claims embraces at least an oligonucleotide primer consisting of SEQ ID NO: 27; a pair of primers consisting of SEQ ID: NO 27; or a pair of primers consisting of SEQ ID NO: 1 and SEQ ID NO: 27, and their methods of use in detecting the presence/absence of *Cladosporium carpophilum*.

Unpredictability and the State of the prior art:

The instant specification is clear in demonstrating the unpredictability in a method of detecting a specific pathogen species employing non-specific primers. Specifically, the instant specification clearly discloses that oligonucleotide consisting of SEQ ID NO: 1 (herein SEQ ID NO: 1) is derived from Internal Transcribed Spacer region which is conserved:

“The conserved fungal ITS region primers are shown in Table 3”

Table 3: Conserved primers designed for amplification of fungal ITS region DNA

Name	Oligo Sequence (5' → 3')	Target	Identifier
ITS1	TCCGTAGGTGAACCTGCGG	Fungal Nuclear rDNA ITS region	SEQ-ID-NO:1
ITS2	GCTGCGTTCTTCATCGATGC	Fungal Nuclear rDNA ITS region	SEQ-ID-NO:2
ITS3	GCATCGATGAAGAACGCAGC	Fungal Nuclear rDNA ITS region	SEQ-ID-NO:3
ITS4	TCCTCCGCTTATTGATATGC	Fungal Nuclear rDNA ITS region	SEQ-ID-NO:4

The fact that SEQ ID NO: 1 is not specific to *Cladosporium carpophilum* is evidenced by the search in the prior art. Beck (U.S. Patent No. 5,800,997, issued September 1, 1998) evidences that instant SEQ ID NO: 1 is 100% homologous over its entire length to a fungal species other than *C. carpophilum* (see SEQ ID NO: 9 of the patent and Sequence Alignment). Such is to be expected since SEQ ID NO: 1 is from a conserved ITS1 region of 18S rDNA (ribosomal DNA).

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Since it is clearly evident that SEQ ID NO: 1 is not specific for detection of *C. carpophilum*, the detection of *C. carpophilum* rests on the oligonucleotide consisting of SEQ ID NO: 27.

However, a search in the prior art shows that SEQ ID NO: 27 is also 100% homologous over its entire length to a fungal species other than *C. carpophilum*. Schnabel et al., (Phytopathology, 1999, vol. 89, no. 1, pages 100-108) evidences that the fungal species to which SEQ ID NO :27 shows 100% homology is disclosed as being the species, *Venturia carpophila* (see also Sequence Alignment).

Amount of Guidance:

The instant invention is drawn to methods of identifying different pathotypes of plant pathogenic fungi. The specification states that the invention provides ITS (Internal Transcribed Spacer) DNA sequences, that shows variability between different fungal pathotypes. (page 4, lines 4-6).

The primers derived from the ITS DNA sequences are disclosed as, "generat[ing] unique fragments in PCR reactions in which the DNA template is provided by specific fungal pathotypes and can thus be used to identify the presence or absence of specific phenotypes in host plant material before the onset of disease symptoms." (page 4, lines 8-11). The specification discloses that the invention includes the ITS sequences of the ribosomal RNA gene regions of particular fungal pathogens as well as primers derived from these regions that are capable of identifying the particular pathogen (page 6, lines 1-4). The primers are disclosed as being derived from the regions of these ITS sequences, "that contain the greatest differences in sequence among the fungal pathotypes." (page 7, lines 8-11). Hence, at last one primer must be unique (that is contain a different sequence) to a specific species so as to allow amplification of

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a specific fungal pathotype.

SEQ ID NO: 1 is disclosed as being derived from ITS1, wherein primers amplify a region (nuclear rDNA ITS region) conserved among fungal pathogens (page 17, lines 14 and 15). SEQ ID NO: 27 is disclosed being derived from ITS region of fungal pathogen species, *Cladosporium carpophilum*, which is explicitly indicated as specifically amplifying *C. carpophilum* (page 21, lines 16-20). The specification discloses that a conserved ITS region primers such as SEQ ID NO: 1 can be used in conjunction with a species specific primer for *C. carpophilum* (SEQ ID NO: 27) (see page 21, lines 20-21).

Absence of Working Example:

The instant specification does disclose the testing of various samples for the presence of *C. carpophilum*, *C. accutatum*, and *Alternaria spp.* using the preferred primer pairs (page 25, lines 5-7). While the various samples were disclosed as being positive for the presence of *C. accutatum* and *Alternario spp.*, none of the sample were positive for *C. carpophilum*.

Level of the Artisan:

The level of a artisan in question is considered to be high.

Quantity of Experimentation:

As discussed above, the instant application is clear in relaying that the claimed oligonucleotides concerning SEQ ID NO: 1 and SEQ ID NO: 27 are *used* for the purpose of detecting *C. carpophilum*. Hence, the make and use criteria of enablement rests on whether the claimed oligonucleotides in fact, can be used for such purpose.

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For such enabling purpose, at least SEQ ID NO: 27 must be specific for the fungal species *C. carpophilum*, so as to distinguish its presence from other fungal pathogen species. However, as the prior art clearly evidences, neither SEQ ID NO: 1 or SEQ ID NO: 27 are specific to *C. carpophilum*. Hence, one skilled in the art would not be able to determine the presence/absence of *C. carpophilum* in a plant sample without undue experimentation because the claimed primers would not be specific to this fungal species.

Conclusion

No claims are allowed.

Inquiries

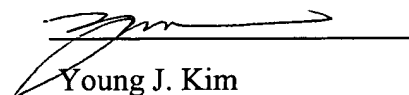
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official

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documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner

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9/26/2005

**YOUNG J. KIM
PATENT EXAMINER**

yjk